

(12) UK Patent Application (19) GB (11) 2 152 387 A

(43) Application published 7 Aug 1985

(21) Application No 8502126

(22) Date of filing 14 Mar 1983

Date lodged 29 Jan 1985

(30) Priority data

(31) 358690 (32) 16 Mar 1982 (33) US

(60) Derived from Application No 8306942 under Section 15(4) of the Patents Act 1977

(71) Applicant
Hollister Incorporated (USA-Illinois),
2000 Hollister Drive, Libertyville, Illinois 60048, United
States of America

(72) Inventor
Marvin Emil Jensen

(74) Agent and/or Address for Service
Saunders & Dolleymore,
2 Norfolk Road, Rickmansworth, Herts WD3 1JH

(61) INT CL⁴
A61F 5/44

(52) Domestic classification
A5R CE

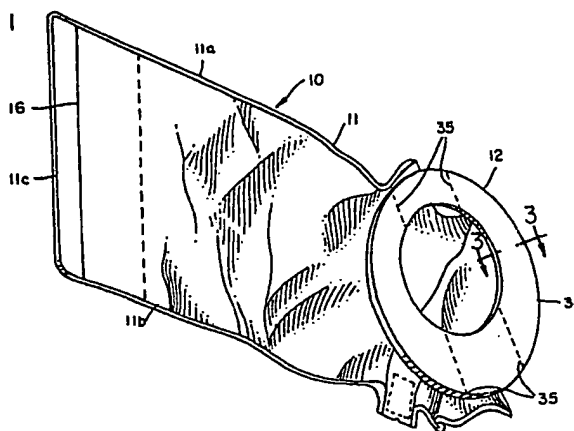
(56) Documents cited
GB A 2082916 GB 1217406
GB A 2000683 GB 1139715
GB 1541565 GB 1117204
GB 1405032 GB 1021145

(58) Field of search
A5R

(54) Fecal collector

(57) The collector (10) comprises a pair of panels of thermoplastic sheet material joined at their margins to define an elongate bag (11) having an opening at one end thereof, and a generally flat ring (12) of soft, pliable, stretchable and contractable closed-cell thermoplastic foam having first and second opposing flat surfaces and having outer and inner marginal edges. The inner marginal edge defines an aperture aligned with the opening of said bag, and the second flat surface of the ring is secured to the bag about the opening. The first flat surface of the ring being coated with a pressure-sensitive water-resistant adhesive. The bag is provided with a vent opening along a marginal portion thereof.

FIG. 1



BEST AVAILABLE COPY

GB 2 152 387 A

2152387

FIG. 1

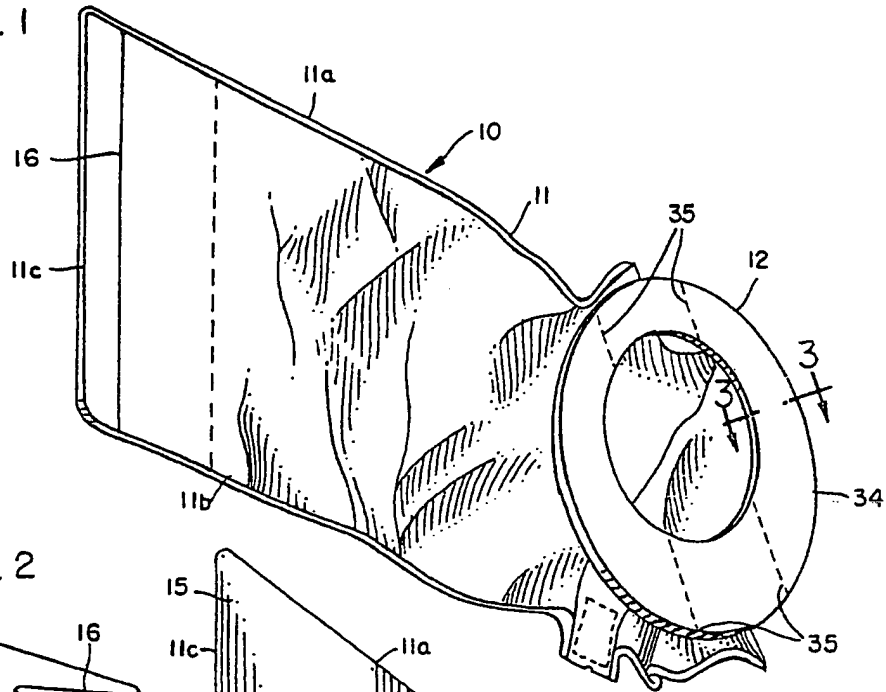


FIG. 2

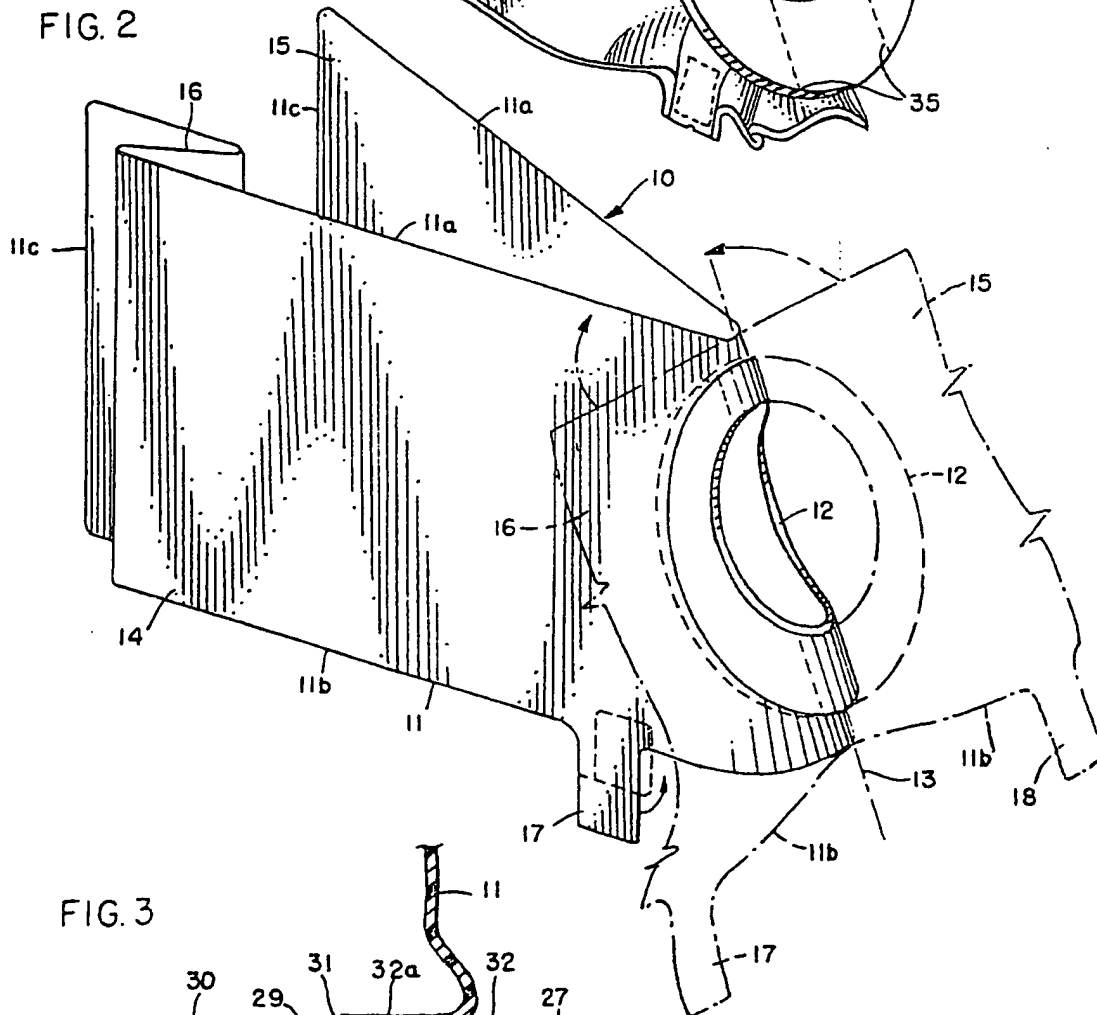
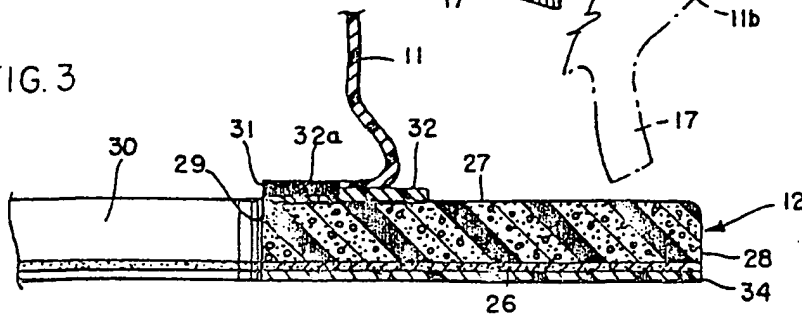
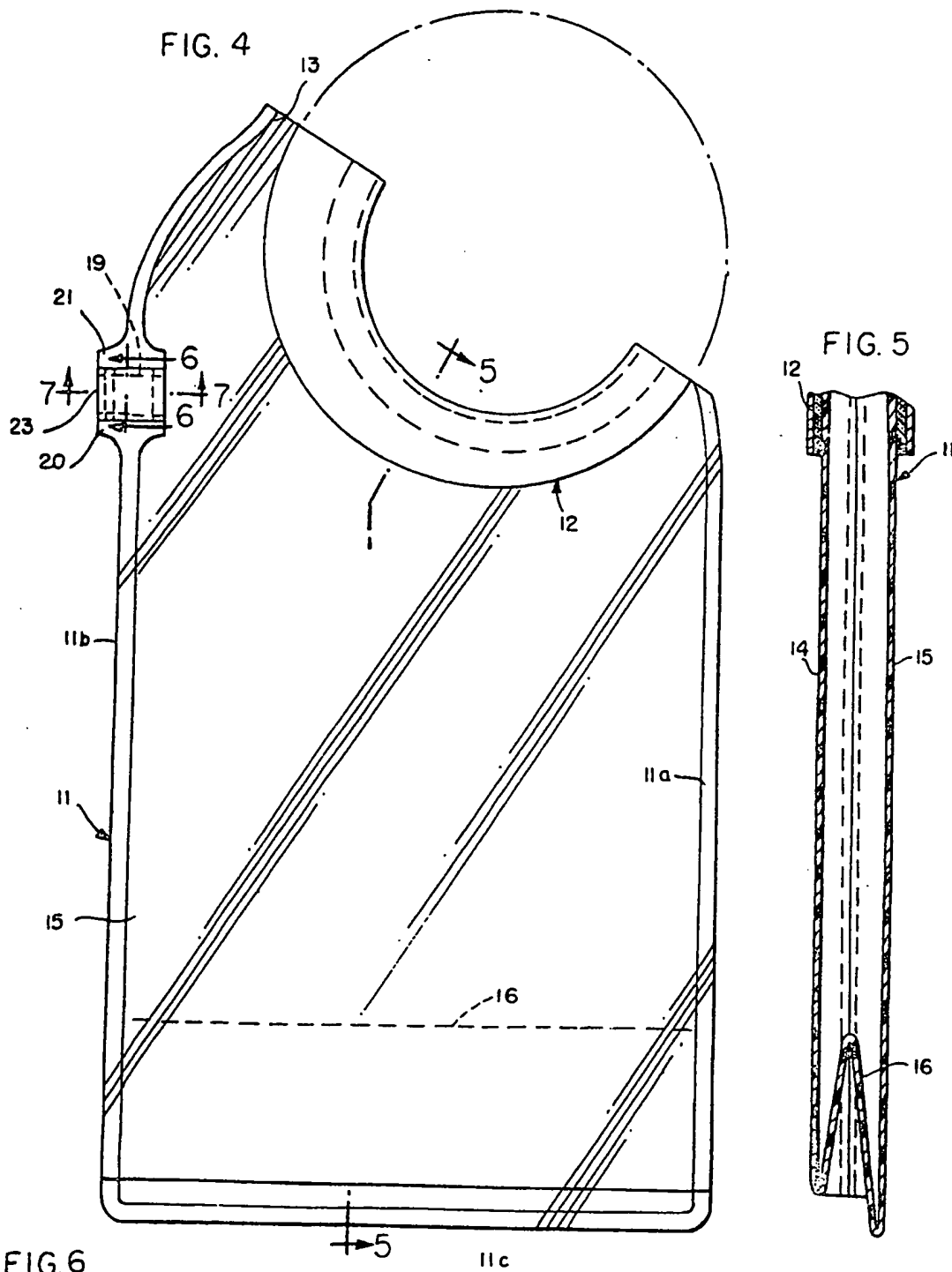
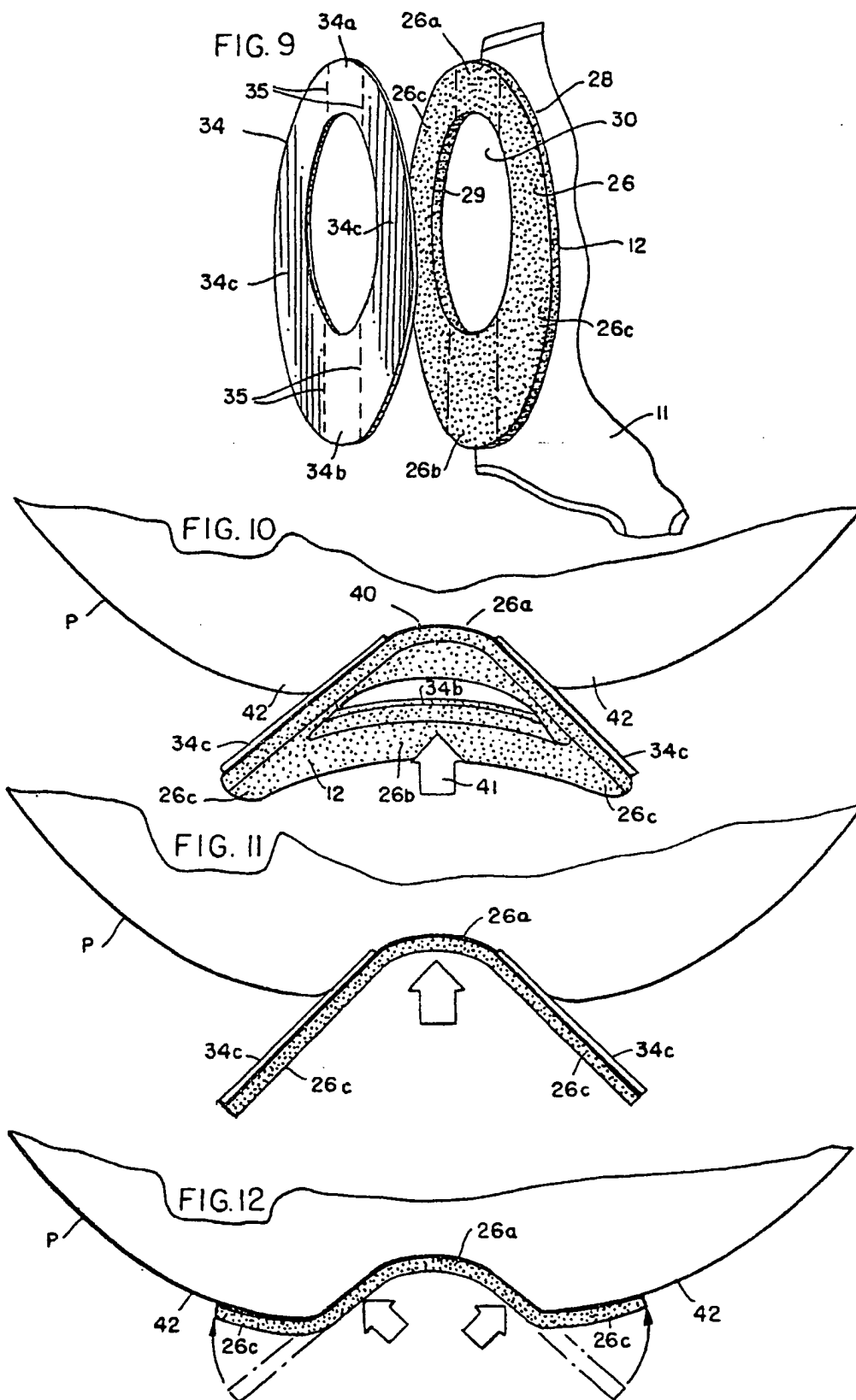


FIG. 3







SPECIFICATION

A fecal collector

5 The invention relates to a fecal collector. While collection bags for incontinent patients are known in the art, such devices have not been free of serious shortcomings. One major problem concerns the formation of an effective external seal about the rectum; various types of adhesive rings have been disclosed but no single design is known for its ease of application and removal, freedom from leakage and unintentional detachment, and adaptability, conformability, and comfort in use. US Patent Specifications Nos. 5,577,989 and 2,491,799 disclose collection bags which are strapped to patients. The manipulation of such straps during attachment and detachment, and the need to move or reposition a patient during such operations, complicates the use of such devices and increases patient inconvenience and discomfort. Devices with adhesive-coated attachment rings, such as disclosed in US Patent Specifications Nos. 3,577,989, 3,734,096, 3,522,807, 3,952,336 and 3,292,626 are also difficult to affix, at least if an effective seal is to be formed, because of the varying contours, and the stretchability, contractability, and softness, of the perianal surfaces. Making adequate sealing contact is only one problem; maintaining such contact is another. If the adhesive used to retain such collectors is aggressive enough to prevent accidental detachment, such collectors may be relatively difficult to remove without causing patient discomfort. Conversely, if a less aggressive adhesive is used to facilitate intentional removal, the possibilities of accidental detachment are increased. In addition, conventional bags are frequently dimensioned and shaped to have inadequate collection capacity or, if of sufficient size, to become twisted and kinked in use, or become wrapped about the leg of a bedridden patient, thereby increasing patient discomfort and the likelihood of accidental detachment.

Other disadvantages are known to persons skilled in the art. The aim of the invention is to avoid, or at least to mitigate, some of these disadvantages.

The invention provides a fecal collector comprising a pair of panels of thermoplastic sheet material joined at their margins to define an elongate bag having an opening at one end thereof; a generally flat ring of soft, pliable, stretchable and contractable closed-cell thermoplastic foam having first and second opposing side surfaces and having outer and inner marginal edges; said inner marginal edge defining an aperture aligned with the opening of said bag, and said second surface of said ring being secured to said bag about said opening; said first surface of said ring being coated with a pressure-sensitive water-resistant adhesive; said bag being provided with a vent opening along a marginal portion thereof.

In a preferred embodiment a foam pad is secured to an internal wall portion of said bag adjacent said vent opening.

Advantageously said marginal portion with said vent opening comprises a flap portion of one of said panels reversely folded to define a pocket facing inwardly into the interior of said bag; said vent opening being located adjacent the folded end of said pocket and said foam pad being disposed within said pocket.

Also the other of the said panels may have a reversely-turned flap portion; said reversely-turned flap portions of the respective panels normally engaging each other but being separable to form a passage therebetween for the insertion of a thermometer or other medical instrument into the interior of said bag. Preferably said foam pad normally urges said first-mentioned flap portion into passage-sealing engagement with said second-mentioned flap portion.

The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings, in which:

Figure 1 is a perspective view of a fecal collector embodying the invention,

Figure 2 is a perspective view of the collector showing (in solid lines) the relationship between the side panels of the bag prior to marginal heat sealing and (in broken lines) the relationship between the bag material and the attachment ring at the time such parts are joined together,

Figure 3 is an enlarged fragmentary sectional view taken along line 3-5 in *Figure 1*,

Figure 4 is a side elevational view of the collector,

Figure 5 is a sectional view taken along line 5-5 in *Figure 4*,

Figure 6 is an enlarged fragmentary sectional view taken along line 6-6 in *Figure 4*,

Figure 7 is an enlarged sectional view taken along line 7-7 in *Figure 4*,

Figure 8 is a sectional view similar to *Figure 7* but illustrating use of the passage for the insertion of a thermometer,

Figure 9 is an exploded fragmentary perspective view of the attachment ring and release sheet showing the relationship between such elements, and

Figures 10 to 12 are a series of simplified and somewhat schematic views illustrating the sequence of steps for properly securing the attachment ring to a patient.

Referring to the drawings, the numeral 10 generally designates a fecal collector in the form of a collection bag 11 having an attachment ring 12. In the preferred embodiment depicted, the bag is formed essentially from a single sheet of odour-barrier thermoplastic film folded along vertical midline 13 to provide a pair of contiguous side panels 14 and 15 (*Figure 2*). The panels are heat sealed together along their upper, lower, and distal edges 11a, 11b, and 11c, respectively. Just prior to such heat sealing, one or both of the panels may be pleated or folded along generally vertical lines, as shown at 16, to increase the capacity of the bag without adding to its length.

It will be noted from *Figure 2* that each of the lower edges 11b of the side panels is contoured to

define a depending tab or flap 17, 18. Prior to heat sealing of the panels, the flaps 17 and 18 are folded upwardly and inwardly to define pockets 17a and 18a, respectively. A foam pad 19 is inserted into one (or both) of the pockets 18a and, during a final heat sealing operation, the panels and flaps are heat sealed together along spaced parallel lines 20 and 21 to define a normally-closed passage 22 (Figures 6 to B) between the opposed flaps 17 and 18B of the respective panels. Venting means 23, in the form of one or more pinholes, are formed in the wall of the pocket 18a that retains the resilient foam pad 19. The pad 19 performs the functions of restraining the outflow of liquids and solids through the vent 23, without at the same time preventing the escape of gases, and of exerting a gentle force against the flap 18B to maintain the passage 22 in closed condition when not in use (Figures 6, 7). To the extent that the excretory contents of the bag may enter and expand the pockets 17a and 18a, the walls of the passage 22 tend to be sealed even more tightly in use. However, should access to the rectal area become necessary for purposes of inserting a thermometer T or other medical instrument, such a procedure may be carried out without detaching the collector from the patient simply by inserting the instrument through the passage 22 (Figure 8) and into contact with the wearer.

The attachment ring 12 is formed preferably of soft, flexible, and stretchable closed-cell thermoplastic foam having normal planar opposite surfaces 26 and 27 (Figure 3) and preferably having generally circular outer and inner margins, respectively. A closed-cell foam of polyethylene having a thickness within the general range of 2 to 10 millimeters (preferably about 3 millimeters) has been found particularly effective, other thermoplastic foam materials such as Polyurethane, or other suitable plastics sheet materials having the described properties of such foams (i.e., softness, pliability, stretchability, and contractability) might be used.

The surface 26 of the foam ring 12 is coated with a layer of pressure-sensitive and water resistant medically-approved adhesive. The tacky adhesive coating is in turn covered by removable release sheets as will be described in detail hereinafter. The inner margin 29 of the foam ring 12 defines a generally circular aperture 50 that is substantially the same size, and is directly aligned with, opening 31 in one end of the elongate plastics bag 11. The bag 11 and ring 12 may be permanently secured together along the inner margin of the ring 12 in any suitable manner. Since the bag 11 and ring 12 are both formed of thermoplastic material, the two may be heat-sealed together along the inner margin of the ring 12. However, to avoid deformation of the foam that might occur during heat sealing, it is believed preferable to adhesively secure the bag 11 to the ring 12 as indicated in Figure 3. Such adhesive attachment is facilitated if a thermoplastic annular liner 32 is first heat sealed to the bag 11 along a heat seal zone 52a extending about the opening 51. Thereafter, the outer surface of the annular liner is adhesively bonded to the foam ring

ring 12.

While the inner margin 29 and the outer margin 28 of the foam attachment ring 12 are preferably circular, they are not concentric. Specifically, the inner margin 29 is displaced upwardly as viewed in Figures 1 and 9, or anteriorly in relation to a patient wearing the collection device. The adhesive-covered surface 26 of the ring 12 therefore has surface portions of different sizes or areas disposed about the aperture 50. Four such portions are depicted in Figure 9 as demarcated by vertical phantom lines along the surface 26. A relatively small perineal portion 26a is located at the upper margin of the ring 12, such portion having a maximum radial width substantially less than the minimum radial width of the diametrically-disposed coccygeal portion 26b. A pair of lateral portions 26c extend between the perineal and lower coccygeal portions 26a and 26b and, as depicted in Figure 9, have circumferential or angular dimensions substantially greater than either of the perineal and coccygeal portions 26a, 26b.

A removable protective covering or release sheet 54 extends over the adhesive-coated surface of the foam ring 12. The covering 34 may be formed of paper, suitably coated with a release layer to permit the covering to be peeled away from the adhesive coating of the ring 12. A polyethylene coating on the paper, to which a silicone coating is applied, has been found effective, but other coating materials such as waxes may be used. As illustrated in Figure 9, the covering 54 has an overall shape and size conforming with the surface 26 of the foam ring 12 and is composed of four individually removable sections or portions, namely, a perineal section 54a covering the perineal portion 26a of the ring, a coccygeal section 54b over the coccygeal portion 26b, and a pair of lateral sections 54c over the lateral portions 26c of the foam ring 12. In the embodiment depicted in the drawings, such sections of the release sheet or covering 34 are defined by lines 35 of perforation that coincide with the phantom lines shown on the ring 12 in Figure 9, and the covering 34 is readily torn along those lines of perforation to permit individual and sequential removal of the sections 34a to 34c; however, it is to be understood that instead of having perforation lines 35 detachably connecting the several sections of the release sheet, those sections may be completely separated from each other so that no tearing apart is required at the time of sequential removal.

The individually-removable sections 34a to 34c of the release sheet 34, and the particular areas or zones of the adhesive-coated ring surface 26 which they cover, greatly facilitate effective attachment of the foam ring 12 to a patient. In such an attachment procedure, the perineal section 34a is first removed to expose the adhesive-coated perineal surface portion 26a of the ring 12, and that portion is pressed into firm contact with the perineal area 40 of patient P as somewhat schematically depicted in Figure 10. During adhesive attachment of the perineal portion 26a of the ring 12 to the perineum of the patient, by pressure applied in the di-

resection of a: row 41, the pliable ring 12 becomes deformed or wedged between the patient's buttocks 42. The coccygeal sheet section 34b is then stripped from the ring 12 (alternatively, it may have been removed from the ring at the time that perineal section 34a was removed) and the exposed adhesive-covered surface of coccygeal ring portion 26b is pressed into contact with the patient's coccygeal area (Figure 11). It is only after the perineal and coccygeal portions 26a and 26b are firmly secured to the patient, with the ring folded between the buttocks as shown in Figure 11, that one of the lateral sections 34c is removed to permit one of the side portions 26c of the ring to become adhesively sealed to the patient. The procedure is then repeated by removing the other lateral section 34c of the release sheet and pressing the other adhesive-covered portion 26c of the ring into sealing contact with the patient (Figure 12). The collection device is thus completely and adhesively sealed to the patient in the perianal area.

The collection bag may be formed of any suitable thermoplastic film or film laminate. For example, flexible walls of the bag may be formed of a polyolefin film laminated with an appropriate gas barrier film. A particularly suitable commercial material comprises low density polyethylene coextruded with a coextensive layer or core of polyvinylidene chloride, but any of a wide variety of other materials may be employed.

CLAIMS

1. A fecal collector comprising a pair of panels of thermoplastic sheet material joined at their margins to define an elongate bag having an opening at one end thereof; a generally flat ring of soft, pliable, stretchable and contractable closed-cell thermoplastic foam having first and second opposing side surfaces and having outer and inner marginal edges; said inner marginal edge defining an aperture aligned with the opening of said bag, and said second surface of said ring being secured to said bag about said opening; said first surface of said ring being coated with a pressure-sensitive water-resistant adhesive; said bag being provided with a vent opening along a marginal portion thereof.

2. A collector according to Claim 1, in which a foam pad is secured to an internal wall portion of said bag adjacent said vent opening.

3. A collector according to Claim 1 or 2, in which said marginal portion with said vent opening comprises a flap. Portion of one of said panels reversely folded to define a pocket facing inwardly into the interior of said bag; said vent opening being located adjacent the folded end of said pocket and said foam pad being disposed within said pocket.

4. A collector according to Claim 3, in which said other of said panels also has a reversely folded flap portion; said reversely folded flap portions of the respective panels normally engaging each other but being separable to form a passage for the insertion of a medical instrument into the interior of said bag.

5. A collector according to Claim 4, in which said foam pad normally urges said first-mentioned flap portion into passage-sealing engagement with said second-mentioned flap portion.

6. A collector according to Claim 1, in which, said bag is provided with a distal end opposite from said one end with at least one of said panels being pleated along fold lines adjacent to but spaced from said distal end for increasing the volumetric capacity of said bag.

7. A collector according to any one of Claims 1 to 6, in which said thermoplastic sheet material of said bag is gas-impermeable to serve as an odour barrier.

8. A fecal collector, constructed, arranged and adapted to operate substantially as herein described with reference to, and as shown in, the accompanying drawings.

Printed in the UK for HMSO, D8818935, 6/85, 7102.
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

BEST AVAILABLE COPY

THIS PAGE BLANK (USPTO)